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Coumaphos (0,0-diethyl 0-(3-chloro-4-methyl 2-oxo-2H-1-benzopryan-7-yl) phosphorothioate Pesticide Registration Standard

(U.S.) Environmental Protection Agency
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0,0-diethyl 0-(3-chloro-4-methyl -2-oxo-2H-1-benzopyran-7-yl) phosphorothioate

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This document contains information regarding reregistration of pesticide products containing O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate (Coumaphos), including how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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Coumaphos

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Pesticide Registration Standard

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Coumaphos Registration Standard

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I

HOW TO REGISTER

UNDER A REGISTRATION STANDARD

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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;
(C) it will perform its intended function without unreasonable adverse effects on the environment; and
(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements. [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29696, July 10, 1978, and 43 FR 37336, August 22, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that are "product specific," i.e., data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and
(B) "generic" data that pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered are all data which are described by all of the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;
(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for reregistration, or to support or maintain an existing registration;
(3) the data are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);
(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and
(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product; that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registration decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps."

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a Section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a "product-by-product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and reissued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II

Regulatory Position

1. Introduction

This chapter describes the Agency's regulatory position on products which contain coumaphos as the sole active ingredient. The Agency's regulatory position incorporates a number of considerations. Foremost among these considerations is an analysis of the registrability of products containing coumaphos based on the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations. The Agency's determination is presented below, and the rationale for this decision follows the position.

In addition to the basic regulatory decision and rationale, this chapter includes the following: criteria for the registration of coumaphos products under the Standard; acceptable ranges and limits for product composition, acute toxicity, and use pattern/application method; required labeling, and a tolerance reassessment.

The scientific basis for decisions presented in this chapter can be found by reading the various disciplinary chapters (Chapters IV-IX) which provide summaries of available scientific data on coumaphos. The data requirements and data gaps are presented in Chapter III. Also, the rationale for requiring data can be found in the footnotes of the tables in Chapter III. References to Agency guidelines for testing are provided when appropriate. In instances where the data requirements differ from the guideline requirements, the rationale is presented in the footnotes of the tables.

2. Description of Chemical

Coumaphos is an insecticide used to control flies, fly larvae, cattle grubs, ticks, lice, fleas, mites, screwworms and fleeceworms on animals. The chemical name for coumaphos is 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate. For convenience in writing this Standard the name "coumaphos" will be used instead of the chemical names. Use of the name coumaphos, however, implies no endorsement of any product containing the active ingredient. Coumaphos is the common name accepted by the International Organization of Standardization (ISO). The American National Standard Institute has not recognized coumaphos as the accepted common name.

Trade names for coumaphos include: Bay 21/199, Asuntol, Muscatox, Resitox, Baymix®, Meldane, Umbethion, and Co-Ral®. (Co-Ral is the registered trademark of the Farbenfabriken Bayer A.G. (MacDougall (19??) MRID 00005526). The technical chemical names for coumaphos are:

a. 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate

b. 0-(3-chloro-4-methyl-7-coumarinyl) 0,0-diethyl phosphorothioate

c. 0,0-diethyl 0-(3-chloro-4-methyl-7-coumarinyl) phosphorothioate

The Chemical Abstracts Registry (CAS) number for coumaphos is 56-72-4. The OPP (Shaughnessey) number is 036501. The molecular formula is $C_{14}H_{16}ClO_5PS$.

3. Regulatory Position for Products Containing Coumaphos as the Sole Active Ingredient

Coumaphos as described in this Standard may be registered for sale, distribution, formulation, and use in the United States. Based on the review of the limited data, the Agency, as of May 12, 1981, finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR) were met or exceeded for coumaphos.

The Agency has considered the limited scientific data obtained from the open literature as of May 12, 1981 and those data submitted by the registrants up through the time of publication of this Standard. The Agency does not have reason to believe that the use of this insecticide will cause unreasonable adverse effects when used in compliance with proper label directions and precautions. Also, at this time, the Agency has no data with which to classify existing coumaphos products. Products will be classified when sufficient data are available. Existing coumaphos products may be reregistered subject to the conditions imposed for data requirements. New coumaphos products may be registered under this Standard, and are subject to the same requirements.

4. Regulatory Rationale

Coumaphos was first registered as a pesticide in 1958. Current annual production in the U.S. amounts to approximately 500,000 lbs. It is used as an insecticide on cattle, livestock, livestock bedding, sheep, goats, horses, dogs, and dog bedding, poultry, poultry housing and poultry litter. It is applied as a dust, spray, dip, pour-on, and backrubber oiler. The products act on the surface of and systemically in the animal. Because the pesticide is used to control certain public health pests on dogs (fleas, lice, and ticks), proof of the efficacy of coumaphos for these uses is a registration requirement (44 FR 27932: May 11, 1979).

Coumaphos is registered under §24(c) of FIFRA for use within the states of New Mexico and California to meet special local needs. Five percent coumaphos dust bags are registered for control of scabies mite on desert bighorn sheep in New Mexico. The twenty-five percent wettable powder is registered for control of scabies mite on cattle in California.

There are limited scientific studies available with which to assess the registrability of all coumaphos products. Available acute toxicity data indicate that: 1) a 50% wettable powder formulation is a severe eye irritant and has a low acute dermal toxicity; and 2) that the oral toxicity of technical coumaphos is high. The data further indicate that a 25% wettable powder formulation has an oral LD_{50} four times more toxic than a 50% wettable powder formulation. The one acceptable chronic effects study demonstrates that coumaphos is not oncogenic in rats and mice. Several studies suggest that coumaphos is a cholinesterase inhibitor in animals although these studies do not meet the Agency's Guidelines for testing (see Chapter VI).

Residues of coumaphos are adequately analyzed in the literature and, as discussed in section 7 of this chapter, do not exceed established U.S. tolerances when the pesticide is applied according to label instructions (see Chapter VIII). Some data are available on the physical/chemical properties of technical coumaphos, but there are major gaps, particularly for the manufacturing-use and end-use products (see Chapter IV). One study is available on ecological effects and there are no data on the environmental fate of coumaphos (see Chapters V and VIII). The efficacy of the compound when used on dogs is partially established in the literature; however, the Agency accepts the compound as being efficacious on dogs based on the well-established efficacy for livestock (see Chapter IX).

Although the data base is incomplete, the Agency has concluded that it should continue the registration for this product for the following reasons:

- No adverse effects have been discovered in the review of the available studies on coumaphos which are not already adequately addressed by FIFRA labeling requirements. Therefore, the benefits demonstrated by the sale of this product outweigh the known risks.
- The nine reported incidents under the Pesticide Incident Monitoring System (PIMS) involving this chemical are poorly documented and do not establish that coumaphos, properly handled and applied, was the cause of the adverse effects.
- When coumaphos is applied according to label directions coumaphos residues do not exceed the established U.S. tolerances.
- The Standard protects against over-exposure to the pesticide in the residential setting by requiring either child-resistant packaging or veterinary use only for residential use products that meet the child resistant packaging criteria.
- The chemical is judged by EPA to be efficacious in controlling fleas, lice, and ticks on dogs and dog bedding.
- In accordance with FIFRA, the Agency's policy is not to cancel routinely the registration of products merely because of a lack of data, or to withhold registration merely because of lack of data. (See Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, publication of the Standard provides a mechanism for identifying data needs and the registration and reregistration requirements. The Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency and the registrability of the chemical will be reassessed.

5. Criteria for Registration Under the Standard

To be subject to this Standard, coumaphos products must meet the following conditions:

- contain coumaphos as the sole active ingredient;
- be within acceptable standards of product composition;
- be within acceptable acute toxicity limits;
- be labeled for acceptable end-uses;
- bear required labeling.

Technical and manufacturing-use coumaphos products must bear label directions for formulation into acceptable end-uses.

The applicant for registration or reregistration of coumaphos products subject to this Standard must comply with all terms and conditions described in this Standard, including commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offer to pay compensation to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of FIFRA, as amended, 7 U.S.C. 136(c)(1)(D) and 136 (c)(2)(D). As discussed in Chapter I, applicants for registration under this Standard must contact the Agency for specific instructions, including updated information on data requirements and companies whose data can be cited and, in the event that these data are cited, to whom compensation must be offered.

A. Technical Coumaphos

1) Product Composition Standards

To be covered under this Standard, the technical product may contain no less than 90% coumaphos as the sole active ingredient. Any technical product submitted for registration containing less than 90% coumaphos as the sole active ingredient will be considered a new product and will not be registrable under this Standard.

2) Acute Toxicity Limits

The Agency will consider registration of technical coumaphos products in the following toxicity categories:

	I	II	III	IV
Acute Oral Toxicity	yes	yes	yes	yes
Acute Dermal Toxicity	yes	yes	yes	yes
Acute Inhalation Toxicity	yes	yes	yes	yes
Primary Eye Irritation	yes	yes	yes	yes
Primary Dermal Irritation	yes	yes	yes	yes

3) Use Patterns

To be covered under this Standard, technical coumaphos products must be labeled for formulation into manufacturing-use products or for formulation into end-use pesticides which are intended for insecticidal applications on animals, animal housing, litter, and bedding.

B. Manufacturing-Use Coumaphos

1) Product Composition Standards

To be covered under this Standard, manufacturing-use coumaphos must contain coumaphos as the sole active ingredient. In addition, all manufacturing-use coumaphos products must not contain impurities other than those in currently registered manufacturing-use products and at no higher concentration than those in currently registered products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registrable under this Standard.

Manufacturing-use products meeting these requirements may contain any percentage active ingredient.

2) Acute Toxicity Limits

The Agency will consider registration of manufacturing-use coumaphos products in the following categories:

	I	II	III	IV
Acute Oral Toxicity	yes	yes	yes	yes
Acute Dermal Toxicity	yes	yes	yes	yes
Acute Inhalation Toxicity	yes	yes	yes	yes
Primary Eye Irritation	yes	yes	yes	yes
Primary Dermal Irritation	yes	yes	yes	yes

3) Use Patterns

To be covered under this Standard, manufacturing-use coumaphos products must be labeled for formulation into end-use pesticides which are intended for insecticidal applications on animals, animal housing, litter, and bedding.

C. End-Use Coumaphos -- Dust, Wettable Powder, Pressurized Spray, Pour-on Liquid, and Emulsifiable Concentrate

1) Product Composition Standards

The following table shows the composition standards end-use coumaphos products must meet to be acceptable under this Standard. In addition, all end-use coumaphos products must not contain inerts and impurities other than those in currently registered end-use products and at no higher concentration than those in currently registered end-use products. Any end-use product not meeting these requirements will be considered a new product and will not be registrable under this Standard.

Formulation	Percent Active Ingredient
Dust (other than dog dust)	up to 5%
Wettable Powder	up to 25%
Pressurized Liquids	up to 3.5%
Pour-on Liquid	up to 4%
Emulsifiable Concentrate	up to 11.9%

The only exception to the above ranges applies to products intended for control of fleas, lice, and ticks on dogs and dog bedding. Such products must not fall below 0.5% of the active ingredient for a dust, 1.0% for a pressurized liquid, and 0.2% for a dip. To be registered for use on dogs, coumaphos products below these concentrations will require the performance or citation of supportive efficacy testing.

Inert ingredients in food-use formulations must be exempted from the requirement of a tolerance (or have tolerances established) under 40 CFR 180.1001. Currently, there are 17 inert ingredients used in coumaphos end-use products that are not exempted under 40 CFR 180.1001(e). These 17 ingredients are listed in the guidance package which accompanies this Standard.

The Agency has identified Freon, a chlorofluorocarbon, as an inert ingredient in certain coumaphos products, from review of current Confidential Statements of Formula. The Agency has banned the use of chlorofluorocarbons in all but critical pesticide products. The Agency does not consider coumaphos a critical product. Therefore, all products containing Freon are not registrable under this Standard.

2) Acute Toxicity Limits

The Agency will consider registration of any end-use coumaphos products for domestic use in the following categories:

	I	II	III	IV
Acute Oral Toxicity	no	no	yes	yes
Acute Dermal Toxicity	no	no	yes	yes
Acute Inhalation Toxicity	no	no	yes	yes
Primary Eye Irritation	no	no	yes	yes
Primary Dermal Irritation	no	no	yes	yes

All coumaphos end-use products intended for domestic use as defined in 40 CFR 162.16(b)(2) in Tox Category III or IV, which meet the child resistant packaging criteria (40 CFR 162.16), must either be packaged for child resistance or be limited to and labeled for veterinary use only.

The Agency will consider registration of any end-use coumaphos products for nondomestic use with the following categories:

	I	II	III	IV
Acute Oral Toxicity	no	yes	yes	yes
Acute Dermal Toxicity	no	yes	yes	yes
Acute Inhalation Toxicity	no	yes	yes	yes
Primary Eye Irritation	no	yes	yes	yes
Primary Dermal Irritation	no	yes	yes	yes

There are no currently registered end-use products in Tox Category I. Any products submitted in this Category would require supporting data, and would not be registrable under this Standard.

3) Use Patterns and Application Methods

To be registered under this Standard, end-use coumaphos products must be labeled as insecticides for one or more of the following uses:

food use	non-food uses
cattle	dogs
goats	dog bedding
swine	livestock bedding
horses	poultry housing
poultry	poultry litter
sheep	

To be registered under this Standard, application rates of coumaphos products must not exceed current levels. This interim restriction is necessary because the data required to evaluate the environmental hazards of all coumaphos products are incomplete. The Agency will reassess maximum application rates of all uses when all data required have been submitted (see Chapter III).

6. Required Labeling

All coumaphos products must bear labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements.

A. Technical and Manufacturing-Use Products

1) Use Pattern Statements

All technical and manufacturing-use products must list on the label the intended end-use of formulated products produced from the technical or manufacturing-use products. In accordance with data to be submitted or cited, all coumaphos technical and manufacturing-use product labels must bear the following statements:

> "For Formulation into an end-use product or an intermediate to be formulated into an end-use product intended for insecticidal use on animals, animal housing, litter, and bedding."

2) Precautionary Statements

Because of the absence of data needed to assess the environmental and health hazards of coumaphos, the Agency cannot evaluate the adequacy of precautionary statements on technical and manufacturing use product labels. Therefore, no changes to current label statements are required at this time. The Agency may, after review of data to be submitted under this Standard, require revisions to current labels and may impose additional label requirements.

B. End-Use Coumaphos Products

Because of the absence of data needed to assess the environmental and health hazards of coumaphos, the Agency cannot evaluate the adequacy of precautionary statements on coumaphos end-use product labels. Therefore, no changes to current label statements are required at this time. Registrants may, at their option, label all wettable powder formulations according to the requirements of Toxicity Category I for eye irritation and thereby be granted a waiver of the requirement for further eye irritation testing (see Chapter III, Table C-2). The Agency may, after review of all data to be submitted under this Standard, require revisions to current labels and may also impose additional label requirements.

7. Tolerance Reassessment

U. S. tolerances are established for residues of the insecticide coumaphos, 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate, and its oxygen analog, 0,0-diethyl 0-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl-phosphate, in or on raw agricultural products as follows: (40 CFR 180.189):

1 ppm in or on meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep

0.5 ppm in milk fat (reflecting negligible residues in milk)

0.1 ppm in eggs.

The tolerance established by the Canadian government is 0.5 ppm in meat, meat by-products and fat of cattle, goats horses, hogs, poultry, and sheep. This is lower than the U.S. tolerance due to different methods of setting tolerances. The Canadian tolerance reflects expected residues that are statistically determined percentages of the maximum residues, rather than the maximum residues used in setting U.S tolerances. Temporary Codex Maximum Residue Levels 1 ppm in poultry and fat of meat of cattle, 0.5 ppm in fat of meat of sheep, pigs, goats, milk, and milk products, and 0.05 ppm in eggs are proposed to be revoked due to a lack of supporting data.

The theoretical maximum residue contribution (TMRC) of total coumaphos in the average American adult diet of milk, meat, fat, milk by-products, and eggs containing the respective U.S. tolerance levels is calculated to be 0.22 mg/day/1.5 kg. Coumaphos applied at the currently registered U.S. application rates will not exceed the established tolerances. However, the Agency is unable to establish an acceptable daily intake (ADI) value for coumaphos because of the absence of acceptable "no-observable-effect level" (NOEL) data. The Agency is, therefore, unable to assess the safety of current tolerances because of the lack of chronic effects data. When the required chronic effects data are submitted (see Toxicology data gaps in Chapter III) the Agency will assess the coumaphos tolerances and revise them as necessary. In the meantime, current U.S. tolerance levels will remain in effect.

III.

Summary of Data Requirements and Data Gaps

Applicants for registration of coumaphos products must cite or submit the information identified as required in the tables in this chapter. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or a formulation.

The tables list the Proposed Guidelines which describe the type of data and when the data are required to be submitted [43 FR, No. 132, 29696 of July 10, 1978; and 43 FR, No. 163, 37336 of August 22, 1978]. Justification for why the test is required is provided in the Guidelines. A discussion of why data additional to that already submitted are necessary, or why data normally required are not necessary for this chemical, are explained in footnotes to the tables. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

Table A-1

Product Chemistry (See Chapter IV)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation [2]	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity and Disclosure of Ingredients	yes	Technical grade of active ingredient (TGAI)	partial	00005526	yes,[1] 8 mos.
163.61-4	Description of manufacturing process	yes	TGAI	yes	00005192, 00005526 05012747, 00005193	no
163.61-5	Discussion on formation of unintentional ingredients	yes	TGAI	yes	05003798, 00005838, 00005207, 00005435, 00005188, 00005189,	no
163.61-6	Declaration and certification of ingredients limits	yes	TGAI	yes	(See 163.61-5)	no
163.61-7	Product analytical methods and data	yes	TGAI	yes	00005433, 00005189 05003798, 00005278 05004290, 00005188, 00005187	no
163.61-8(1)	Color	yes	TGAI	yes	00005193, 00005307, 00005417, 00021981, 00005190, 00005526	no
163.61-8(2)	Odor	yes	TGAI	yes	(See 163.61-8(1))	no
163.61-8(3)	Melting Point	yes	TGAI	yes	(See 163.61-8(1))	no

Table A-1 (Cont'd)

Product Chemistry (See Chapter IV)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation [1]	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(4)	Solubility	yes	Technical grade of active ingredient (TGAI)	partial	(See 163.61-8(1))	yes,[2] 8 mos.
163.61-8(5)	Stability	yes	TGAI	yes	(See 163.61-8(1))	no
163.61-8(6)	Octanol/Water partition coefficient	yes	TGAI	no	(See 163.61-8(1))	yes, 8 mos.
163.61-8(7)	Physical State	yes	TGAI	yes	(See 163.61-8(1))	no
163.61-8(8)	Density or Specific Gravity	yes	TGAI	no	(See 163.61-8(1))	yes, 8 mos.
163.61-8(9)	Boiling Point	yes	TGAI	yes	(See 163.61-8(1))	no
163.61-8(10)	Vapor Pressure	yes	TGAI	yes	(See 163.61-8(1))	no
163.61-8(11)	pH	yes	TGAI	no	(See 163.61-8(1))	yes, 8 mos.
163.61-8(12)	Storage Stability	no				

Table A-1 (Cont'd)

Product Chemistry (See Chapter IV)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation 3/	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(13)	Flammability	no				
163.61-8(14)	Oxidizing or Reducing Action	no				
163.61-8(15)	Explosiveness	no				
163.61-8(16)	Miscibility	no				
163.61-8(17)	Viscosity Coefficient	no				
163.61-8(18)	Corrosion Characteristics	no				
163.61-9(19)	Dielectric Breakdown Voltage	no				
163.61-9	Submittal of samples	no				

Footnotes

Table A-1

Product Chemistry

Generic Data Requirements

Coumaphos

1/ Certification that the ingredient statement accurately reflects current production is required.

2/ A quantitative description of Solubility is required.

3/ The following studies were used in developing the Standard. Although they are not cited in support of a specific Guideline requirement, they were generally used:

05006145, 05010317, 05002073, 00005208, 00005528,
05002075, 00005336, 05002340, 05004089, 05005130,
05002360, 05004866, 00021997, 05014477, 05010318,
05003797, 00005298, 05003798.

Table A-2

Environmental Fate (See Chapter V)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.62-7(b)	Hydrolysis	yes	Radio-labeled analytic grade or technical grade of active ingredient (RLAG/TGAI)	no[1]		yes, 8 mos.
163.62-7(c)	Photodegradation	yes	RLAG/TGAI	no		yes, 8 mos.
163.62-8(b)	Aerobic Soil Metabolism	yes	RLAG/TGAI	no		yes, 26 mos.
163.62-8(c)	Anaerobic Soil Metabolism	yes	RLAG/TGAI	no		yes, 26 mos.
163.62-8(d)	Anaerobic Aquatic Metabolism	no				
163.62-8(e)	Aerobic Aquatic Metabolism	no				
163.62-8(f)	Microbial Metabolism:					
	(1) Effects of Microbes on Pesticides	reserved[2]				
	(2) Effects of Pesticides on Microbes	reserved[2]				

Table A-2 (Cont'd)

Environmental Fate (See Chapter V)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Requried For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.62-8(g)	Activated Sludge	reserved[2]				reserved[2]
163.62-9(b)	Leaching	yes[3]	Technical grade of the active ingredient (TGAI)	no		yes, 14 mos.
163.62-9(c)	Volatility	yes[4]	TGAI	no		yes, 14 mos.
163.62-9(d)	Adsorption/ Desorption	yes[5]	TGAI	no		yes, 14 mos.
163.62-9(e)	Water Dispersal	yes	A representative formulation type	no		yes, 14 mos.
163.62-10(b)	Terrestrial Field Dissipation:					
	(1) Field & Vegetable Crops	reserved[6]		no		
	(2) Tree Fruit & Nut Crops Uses	reserved[6]		no		
	(3) Pasture Land Uses	reserved[6]		no		
	(4) Domestic Outdoor Parks, Ornamental & Turf Uses	no				

Table A-2 (Cont'd)

Environmental Fate (See Chapter V)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Stnadard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.62-10(f)	Combination & Tank Mix Field Dissipation	no				
163.62-10(g)	Long Term Field Dissipation Study	no				
163.62-11(b)	Accumulation in Rotational Crops	reserved[6/]				
163.62-11(c)	Accumulation in Irrigated Crops	no				
163.62-11(d)	Fish Accumulation	yes	Radio-labeled analytic grade or technical grade of the active ingredient	no		yes, 14 mos.
163.62-11(e)	Special Studies Accumulation in Aquatic Noncrop	no				
163.62-13	Disposal & Storage	reserved[2/]				
Special	Composition and concentration in feces	yes[7/]	A representative formulation - type	no		yes, 14 mos.

Table A-2 (Cont'd)

Environmental Fate (See Chapter V)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
	(5) Rights of Way, Shelterbelts & Related Uses	no				
163.62-10(c)	Aquatic Field Dissipation:	no				
	(1) Aquatic Food Crop Uses	no				
	(2) Aquatic Non-crop Uses	no				
	(3) Specialized Aquatic Uses	no				
163.62-10(d)	Terrestrial/ Aquatic (Forest) Field Dissipation	no				
163.62-10(e)	Aquatic Impacts Uses:					
	(1) Direct Discharge	no				
	(2) Indirect Discharge	no				
	(3) Wastewater Treatment	no				

Footnotes

Table A-2

Environmental Fate

Generic Data Requirements

Coumaphos

1/ One hydrolysis study (MRID 05004309) was reviewed and found scientifically invalid because of the lack of detailed information concerning experimental conditions, including temperature, darkness, and sterility of the samples. In addition, discrepancies were found in the calculated data dealing with levels of degraded coumaphos.

2/ The requirement for submission of these data is currently being reserved pending the review and modification of the testing protocols.

3/ The mobility of the test substance and its degradates in soil shall be assessed either by soil thin layer chromatography, soil column, or batch equilibrium (adsorption/desorption) procedures. The use of coumaphos in dip vaps and disposal of vat contents into the environment justifies this data requirement, as well the use of dust bags (particularly in feed lots).

4/ Laboratory volatility studies using nonradioisotopic analytical techniques are required to support the registration of all formulated products intended for henhouse use, (to which the greenhouse use referred to in 163.62-9(c) is similar) and to evaluate reentry hazards from cholinesterase-inhibiting pesticides, such as the health studies indicate for coumaphos.

5/ This requirement will be met by data provided on leaching.

6/ Data may be required pending the outcome of special studies of composition and concentration in feces.

7/ Data are required to show the maximum concentration of coumaphos and its degradation products in chicken litter and livestock manure at the time such materials are applied as fertilizer.

Table A-3

Ecological Effects (See Chapter VI)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.71-1	Avian Single Dose Oral LC_{50}	yes	Technical grade of the active ingredient (TGAI)	no		yes, 8 mos.
163.71-2	Avian Dietary LC_{50}	yes	TGAI	no		yes, 8 mos.
163.71-3	Mammalian Acute Toxicity	no				
163.71-4	Avian Reproduction	no				
163.71-5	Simul. & Actual Field Testing for Mammals/Birds	no				

Table A-3 (Cont'd)

Ecological Effects (See Chapter VI)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.72-1	Fish Acute LC_{50}	yes	Technical grade of the active ingredient	no		yes, 8 mos.
163.72-2	Acute Toxicity to Aquatic invertebrates	yes	"	yes	05009242	no
163.72-3	Acute Toxicity to to Estuarine & Marine Organisms	no				
163.72-4	Embryolarvae & Life-Cycle	no				
163.72-5	Aquatic Organ. Tox. & Residue Studies	no				
163.72-6	Simul. & Actual Field Testing for Aquatic Organisms	no				

Table A-4

Toxicology (See Chapter VI)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	yes	Technical grade of the active ingredient (TGAI)	yes	00005496 GS0018-004 GS0018-003	no
163.81-2	Acute Dermal Toxicity	yes	TGAI	no		yes, 8 mos.
163.81-3	Acute Inhalation Toxicity	yes	TGAI	no		yes, 8 mos.
163.81-4	Primary Eye Irritation	yes	TGAI[1]	no		yes, 8 mos.
163.81-5	Primary Dermal Irritation	yes	TGAI[1]	no		yes, 8 mos.
163.81-6	Dermal Sensitization	yes	TGAI[1]	no		yes, 8 mos.

Table A-4 (Cont'd)

Toxicology (See Chapter VI)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.83-1	Chronic Feeding	yes	Technical grade of the active ingredient (TGAI)	no[8/]		yes, 50 mos.
163.83-2	Oncogenicity	yes	TGAI	yes	05009938	no
163.83-3	Teratogenicity	yes	TGAI	no		yes, 26 mos.
163.83-4	Reproduction	yes	TGAI	no[9/]		yes, 38 mos.
163.84-(2-4)	Mutagenicity	yes	TGAI	no		yes, 26 mos.
163.85-1	Metabolism	yes	Double-labeled compound	partial	05004087 05012220	yes[10/], 26 mos.
163.86-1	Domestic Animal Safety Testing	no				

Table A-4 (Cont'd)

Toxicology (See Chapter VI)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-7	Acute Delayed Neurotoxicity	yes[2]	Technical grade of the active ingredient (TGAI)	no		yes, 14 mos
163.82-1	Subchronic Oral Toxicity	yes	TGAI	no[3]		yes, 14 mos.
163.82-2	Subchronic (21-day) Dermal	no[4]				
163.82-3	Subchronic 90-day Dermal Toxicity	yes[5]	Technical grade of the active ingredient	no		yes, 14 mos.
163.82-4	Subchronic Inhalation Toxicity	reserved[6]				
163.82-5	Subchronic Neurotoxicity	reserved[7]				

Footnotes

Table A-4

Toxicology

Generic Data Requirements

Coumaphos

1/ Data are required on the technical chemical to provide a basis for comparison with the end-use product testing.

2/ Data are required because coumaphos is a cholinesterase inhibitor.

3/ Two studies (MRID 00005384 & MRID 00005504) were reviewed and found to be insufficient to meet the data requirements. MRID 00005384 lacked histopathology and MRID 00005504 should have been performed on weanling rats in order to determine coumaphos' toxicity during physical and sexual development.

4/ The subchronic 90-Day Dermal Toxicity Study (163.82-3) is required instead.

5/ Data are required because coumaphos is used on dogs and dog bedding and thus presents the potential for direct application to human skin.

6/ Testing is required if results from acute inhalation tests are positive.

7/ Testing is required if results from acute delayed neurotoxicity tests are positive.

8/ One study (MRID 00005473) was reviewed and found inadequate. The histopathology was inadequate with only 5 animals per dose being studied. No clinical studies were performed.

9/ One study (MRID 00005148) was reviewed and found not to meet the data requirements due to inadequate histopathology.

10/ Two studies (MRID 00004087 & MRID 05012220) provided some information on the identity of major metabolites and routes of elimination but no data are available to assess the absorption of coumaphos as a function of dose and duration of exposure. No information was provided on the disposition of the leaving group. Testing is required with the double-labeled compound (^{32}P and ^{14}C) to determine the fate of the parent compound and leaving group.

Table A-5

Residue Chemistry (See Chapter VII)

Generic Data Requirements

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation */	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
-	Metabolism in plants	no		-		-
-	Metabolism in Animals	yes	A representative formulation type (RFT)	yes	See footnote 1/	no
-	Analytical Methods	yes	RFT	yes	See footnote 2/	no
-	Residue Data: Crops-	no		-		-
-	Residue Data: Processed Crops-	no		-		-
-	Residue Data: Milk and Meat and Eggs	yes	RFT	yes	See footnote 3/	no
-	Storage and Stability	yes	RFT	yes	00005190	no

July, 1981

Footnotes

Table A-5

Residue Chemistry

Generic Data Requirements

Coumaphos

1/ 05004087, 00005454, 00005323, 05003806, 05012748,
05004483, 00005401, 05003806, 00005332, 00005392,
05100522, 05008968, 00005450

2/ 05004066, 00005308, 00005328, 00005342, 00005289,
00005438, 00005080, 00005509, 05004211, 05017521,
05006630, 00005437

3/ 00005293, 00005329, 05006630, 00005295, 00005331,
00005338, 00005186, 00005056, 00005493, 05012915,
05004690, 00005509, 00005080, 00005336, 00005081,
00005333, 00005830, 00005510, 05005830, 00005051,
00005396, 00005395, 00005511, 00005339, 00005399,
00005479, 00005822, 00005047, 05005125, 00005048,
00005831, 00005483, 00005485, 00005832, 00005833,
00005834, 00005214, 05010096, 00005491, 00005317,
00005235, 00005082, 00005074, 00005490, 00005486,
00005040, 00005042, 00005492, 00005441, 00005437,
00005456, 00005453, 00005448, 05004066, 00005440,
00005451, 05010354, 00005480, 00005840, 00005842,
00005161, 00005400, 00005456, 00005458

4/ The following studies were used in developing the Standard. Although they are not cited in support of a specific Guideline requirement, they were generally used: 05002359, 05016099, 00005439, 0500???? Knapp, 05004087, 00005402, 05108561, 05003799, 05006806.

Table B-1

Product-Chemistry (See Chapter IV)

Product-Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity and disclosure of Ingredients	yes	Each product	no		yes, 8 months
163.61-4	Description of manufacturing process	yes	Each product	no		yes, 26 months
163.61-5	Discussion on formation of unintentional ingredients	yes	Each product	no		yes, 26 months
163.61-6	Declaration and certification of ingredients limits	yes	Each product	no		yes, 8 months
163.61-7	Product analytical methods and data	yes	Each product	no		yes, 8 months
163.61-8(1)	Color	no				
163.61-8(2)	Odor	no				
163.61-8(3)	Melting Point	no				

Table B-1 (Cont'd)

Product-Chemistry (See Chapter IV)

Product Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(4)	Solubility	no				
163.61-8(5)	Stability	no				
163.61-8(6)	Octanol/Water partition coefficient	no				
163.61-8(7)	Physical State	yes	Each product	no		yes, 8 mos.
163.61-8(8)	Density or Specific Gravity	yes	Each product	no		yes, 8 mos.
163.61-8(9)	Boiling Point	no				
163.61-8(10)	Vapor Pressure	no				
163.61-8(11)	pH	yes	Each product	no		yes, 8 mos.
163.61-8(12)	Storage Stability	yes	Each product	no		yes, 8 mos.

Table B-1 (Cont'd)

Product-Chemistry (See Chapter IV)

Product-Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(13)	Flammability	yes[1/]	Each product	no		yes, 8 mos.
163.61-8(14)	Oxidizing or Reducing Action	yes[2/]	Each product	no		yes, 8 mos.
163.61-8(15)	Explosiveness	yes[3/]	Each product	no		yes, 8 mos.
163.61-8(16)	Miscibility	yes[4/]	Each product	no		yes, 8 mos.
163.61-8(17)	Viscosity Coefficient	yes[5/]	Each product	no		yes, 8 mos.
163.61-8(18)	Corrosion Characteristics	yes	Each product	no		yes, 8 mos.
163.61-9(19)	Dielectric Breakdown Voltage	no				
163.61-9	Submittal of samples	no				

Footnotes

Table B-1

Product Chemistry

Product-Specific Chemistry Data Requirements for

Manufacturing-Use Products

Coumaphos

1/ For each product containing a volatile, flammable ingredient.

2/ For each product containing an oxidizing or reducing agent as an ingredient.

3/ For each product containing a potentially explosive ingredient.

4/ For emulsifiable products which may be diluted with petroleum solvents.

5/ For liquid formulations.

Table B-2

Toxicology (See Chapter VI)

Product-Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?1/	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	no				
163.81-2	Acute Dermal Toxicity	no				
163.81-3	Acute Inhalation Toxicity	no				
163.81-4	Primary Eye Irritation	no				
163.81-5	Primary Dermal Irritation	no				
163.81-6	Dermal Sensitization	no				

1/ Data are required on the technical product for extrapolation to the manufacturing-use product.

Table B-2 (Cont'd)

Toxicology (See Chapter VI)

Product-Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?[1]	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-7	Acute Delayed Neurotoxicity	no				
163.82-1	Subchronic Oral Toxicity	no				
163.82-2	Subchronic (21-day) Dermal	no				
163.82-3	Subchronic 90-day Dermal Toxicity	no				
163.82-4	Subchronic Inhalation Toxicity	no				
163.82-5	Subchronic Neurotoxicity	no				

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[1] Data are required on the technical product for extrapolation to the manufacturing-use product.

Table B-2 (Cont'd)

Toxicology (See Chapter VI)

Product-Specific Data Requirements for Manufacturing-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?[1]	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.83-1	Chronic Feeding	no				
163.83-2	Oncogenicity	no				
163.83-3	Teratogenicity	no				
163.83-4	Reproduction	no				
163.84-(2-4)	Mutagenicity	no				
163.85-1	Metabolism	no				
163.86-1	Domestic Animal Safety Testing	no				

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[1] Data are required on the technical chemical for extrapolation to the manufacturing-use product.

Table C-1

Product-Chemistry (See Chapter IV)

Product-Specific Data Requirements for End-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity and disclosure of Ingredients	yes	Each product	no		yes, 8 months
163.61-4	Description of manufacturing process	yes	Each product	no		yes, 26 months
163.61-5	Discussion on formation of unintentional ingredients	yes	Each product	no		yes, 26 months
163.61-6	Declaration and certification of ingredients limits	yes	Each product	no		yes, 8 months
163.61-7	Product analytical methods and data	yes	Each product	no		yes, 8 months
163.61-8(1)	Color	yes	Each product	no		yes, 8 months
163.61-8(2)	Odor	yes	Each product	no		yes, 8 months
163.61-8(3)	Melting Point	no				

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Table C-1 (Cont'd)

Product-Chemistry (See Chapter IV)

Product-Specific Data Requirements for End-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(4)	Solubility	no				
163.61-8(5)	Stability	no				
163.61-8(6)	Octanol/Water partition coefficient	no				
163.61-8(7)	Physical State	yes	Each product	no		yes, 8 months
163.61-8(8)	Density or Specific Gravity	yes	Each product	no		yes, 8 months
163.61-8(9)	Boiling Point	no				
163.61-8(10)	Vapor Pressure	no				
163.61-8(11)	pH	yes	Each product	no		yes, 8 months
163.61-8(12)	Storage Stability	yes	Each product	no		yes, 8 months

Table C-1 (Cont'd)

Product-Chemistry (See Chapter IV)

Product-Specific Data Requirements for End-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(13)	Flammability	yes[1/]	Each product	no		yes, 8 mos.
163.61-8(14)	Oxidizing or Reducing Action	yes[2/]	Each product	no		yes, 8 mos.
163.61-8(15)	Explosiveness	yes[3/]	Each product	no		yes, 8 mos.
163.61-8(16)	Miscibility	yes[4/]	Each product	no		yes, 8 mos.
163.61-8(17)	Viscosity Coefficient	yes[5/]	Each product	no		yes, 8 mos.
163.61-8(18)	Corrosion Characteristics	yes	Each product	no		yes, 8 mos.
163.61-9(19)	Dielectric Breakdown Voltage	no				
163.61-9	Submittal of samples	no				

July, 1981

Footnotes

Table C-1

Product Chemistry

Product-Specific Chemistry Data Requirements for End-Use Products

Coumaphos

1/ For each product containing a volatile, flammable ingredient.

2/ For each product containing an oxidizing or reducing agent as an ingredient.

3/ For each product containing a potentially explosive ingredient.

4/ For emulsifiable products which may be diluted with petroleum solvents.

5/ For liquid formulations.

Table C-2

Toxicology (See Chapter VI)

Product-Specific Data Requirements for End-Use Products

Coumaphos

Guidelines Citation	Name of Test	Are Data Required For this Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	yes	Each product1/	yes	00035416	yes, 8 mos.
163.81-2	Acute Dermal Toxicity	yes	Each product1/	no		yes, 8 mos.
163.81-3	Acute Inhalation Toxicity	yes2/	Each product1/			yes, 8 mos.
163.81-4	Primary Eye Irritation	yes3/	Each product1/	no		yes, 8 mos.
163.81-5	Primary Dermal Irritation	yes	Each product1/	no		yes, 8 mos.
163.81-6	Dermal Sensitization	yes	Each product1/	no		yes, 8 mos.

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Footnotes

Table C-2

Toxicology

Product-Specific Date Requirements for End-Use Products

Coumaphos

1/ The Agency has the option of combining end-use products into groups of "substantially similar" products and requiring testing on only one product in the groups. Groups are made up of end-use products of similar concentrations and formulation type. This reduces the testing burden imposed on the registrant. In the case of coumaphos, however, available toxicity data show that products may not necessarily be rationally grouped by conventional means.

Acute oral toxicity studies with technical coumaphos have demonstrated that the toxicity of the compound varies with the physical form of the chemical and the vehicle in which the oral administration is made (Hecht 1958, GS0018003). Studies have also shown that a 25% wettable powder formulation is four times more toxic than a 50% wettable powder formulation (Lamb and Anderson, 1974, MRID 00005416, Hecht, 1958, GS0018003). The Agency would be willing to consider combining coumaphos end-use formulations into groups of substantially similar products if the above anomalies in the oral toxicity data can be explained. Otherwise, testing is required on each coumaphos end-use formulation.

2/ Testing is required if products are found to produce a respirable vapor, or if 20% more of the aerodynamic equivalent is composed of particles not larger than 10 microns.

3/ One study (MRID 00005414) has shown that a 50% wettable powder formulation causes eye irritation and corneal damage in rabbits at 21 days, placing the formulation in Toxicity Category I. The Agency will waive primary eye irritation testing for other coumaphos wettable powder formulations if registrants agree to place Toxicity Category I precautionery statements on the end-use product labels.

Table C-3

Efficacy (See Chapter IX)

Product-Specific Data Requirements for End-Use Products

Coumaphos

Site Citation	Name of Pest	Are Data Required For This Standard?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
Dogs	fleas	yes	0.5% Dust	yes	00005344 00005326, 00005211	no
			1.0% Pressurized Liquid	yes	00005087	no
	lice	yes	0.5% D	no[1]		no
			1.0% PrL	yes	00005088	no
	ticks	yes	0.5% D	yes	GS0018-001	no
			1.0% PrL	yes	00005087	no
Dog bedding	fleas	yes	0.5% D	yes	GS0018-001	no
			1.0% PrL	yes	00005087	no
	lice	yes	0.5% D	no[1]		no
			1.0% PrL	yes	00005088	no
	ticks	yes	0.5% D	yes	GS0018-001	no
			1.0% PrL	yes	00005087	no

Footnotes

Tables C-3

Efficacy

Product-Specific Data Requirements for End-Use Products

Coumaphos

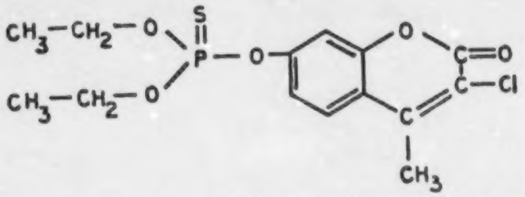
1/ Efficacy of the .5% dust formulation for control of lice on dogs and dog bedding is assumed due to extrapolation from efficacy studies done on lice infesting larger agricultural animals and their bedding (MRID 00005352, 05011422, 00005028, 00005033, 00005200).

IV

Product Chemistry

Product Chemistry Summary - Technical Coumaphos

Coumaphos is synthesized by reacting diethyl phosphorothionochloridate with 3-chloro 4 methyl-7-hydroxycoumarin (chlorferron) at 50-100°C and atmospheric pressure, in the presence of a suitable solvent, and acid-binding agent and finely divided copper as a catalyst. After the reaction the mixture is cooled, filtered, the product is recovered by evaporating the solvent (Sittig Manual (1977) Noise Data Crop. Park Ridge, N.J.). In addition confidential data describing the coumaphos manufacturing process have been review by the Agency (MRID 00005192). The molecular structure of coumaphos is:



The Agency has reviewed the available information on ultraviolet spectrophotometric methods (MRID 05004290, 00005188, 00005187) and found them adequate for the identification and quantitation of coumaphos in the technical, manufacturing-use, and end-use products. Methods are also available for the analysis of certain impurities (MRID 00005433, 00005189, 05003798, 00005278).

There are 17 inert ingredients used in coumaphos end-use products that are not cleared for use on animals under 40 CFR 180.1001(e). Registrants of end-use products with inert ingredients that have not been cleared must either remove the ingredient from the product or obtain clearance from the Agency. The Agency has found one inert ingredient, Freon, a chlorofluorocarbon, to be unacceptable for use in end-use pesticide products because of its potential to deplete the ozone layer of the atmosphere (see 43 CFR 11318).

Physical and Chemical Properties

Some data are available on the physical and chemical properties of coumaphos. Data which are not available but which are required to be submitted are listed in the tables in Chapter III. Available data on technical coumaphos are as follows:

Color:	tan
Odor:	weak but not unpleasant
Melting Point:	90 92°C
Solubility:	insoluble in water, soluble in aromatic solvents, less soluble in alcohols and ketones.
Stability:	stable under normal use conditions, hydrolyzes slowly under alkaline conditions.

Physical State: crystalline solid

Boiling Point: $20^{\circ}C$ at approx. 1×10^{-7} mm Hg

Vapor Pressure: 1×10^{-7} mm Hg at $20^{\circ}C$

The above physical and chemical properties for technical coumaphos were reported under MRID 00005193, 00005307, 00005417, 00021981, 00005190, 00005526.

Summary of Major Data Gaps

The major data gaps for this chemical are: clarification of ingredient statements, solubility in quantitative amounts, octanol/water partition coefficient, density or specific gravity, pH for the technical product,* certain physical and chemical properties for manufacturing-use and end-use coumaphos products and certain product chemistry data on end-use products.

* Depending on solubility in water, which is not known in quantitative terms.

V.

Environmental Fate

Use Profile

Coumaphos is an insecticide registered for use on livestock and livestock bedding, poultry, poultry housing, poultry litter, dogs, and dog bedding.

One technical coumaphos product and three manufacturing-use products are registered. Coumaphos is formulated into end-use products as a dust, wettable powder, pressurized liquid, emulsifiable concentrate, ready-to-use pour-on, ready-to-use spray, spray foam, spray concentrate and backrubber oiler. The registration of a new flowable product is pending. Some coumaphos products are applied topically and act to control external pests; others are applied topically but act systemically to control internal parasites. Coumaphos products are sometimes applied to livestock using dust bags or dip vats. There are several other registered application methods and numerous registered concentrations.

Approximately 500,000 lbs. of coumaphos are produced in the United States annually. Approximately 60% is formulated into emulsifiable concentrates and wettable powders, 36% into dusts, 2% into ready-to-use solutions, and 1% into pressurized liquids. Beef cattle account for 87% of coumaphos use and dairy cattle account for 12%; emulsifiable concentrates and wettable powders are the primary formulations used on cattle. Use on other livestock, poultry, and dogs account for the remaining 1% of coumaphos use.

Environmental Fate Summary

There is one scientifically valid study on the environmental fate of coumaphos. Coumaphos (purity unspecified) applied at 2 and 100 ppm inhibited the respiration of Azotobacter vinelandii, a nitrogen-fixing bacterium, by 50% and 33% respectively (MacRae and Celo 1974, MRID 05005579). The authors did not address the apparent contradiction that higher concentrations result in lower respiratory inhibition. No conclusions about the environmental fate of coumaphos can be drawn from this study.

Exposure Profile

Because of the absence of data on the exposure and environmental fate of coumaphos, it is not possible to quantitatively assess exposure of humans and wildlife to coumaphos. Mixers and applicators of coumaphos formulations are at risk of the highest direct exposures. Dermal and eye exposure can result from splashing during the diluting, mixing, and use of emulsifiable concentrates and wettable powders. Respiratory exposure could occur from "puff back" during handling of dusts and wettable powders. The potential for respiratory exposure after application cannot be assessed due to the lack of vapor pressure data.

The general public and domestic animals are exposed to coumaphos because it is registered for use on dogs and dog bedding. The use of coumaphos on meat and dairy livestock and poultry also results in dietary exposure to the general public; see Chapter VII, Residue Chemistry, for a discussion of dietary exposure to coumaphos. The use of coumaphos-contaminated poultry litter and manure as fertilizer on field and vegetable crops, tree fruit and nut crops, and pasture land, presents the potential for human dietary and non-dietary exposure. This potential was not evaluated due to the lack of data.

Summary of Major Data Gaps

The major data gaps for this chemical are hydrolysis, soil metabolism, leaching, volatility, adsorption/desorption, water dispersal, fish accumulation, photodegradation, and composition and concentration in feces.

VI

Toxicology

Toxicology Summary - Technical Coumaphos

Acute Toxicity

Studies have shown that technical coumaphos has a very high acute oral toxicity and is classified as Toxicology Category 1. Acute oral toxicities in rats have been reported ranging from 17.1 to 87.0 mg/kg depending on sex, physical form of the chemical, and the method of administration used (Narcisse 1976, MRID 00005496, Johnston and Scott 1965, GS0018-004, Hecht 1958, GS0018-003).

Subchronic Toxicity

Inadequate studies assessing the subchronic toxicity report a no-observable-effect level (NOEL) equal to or less than 2 ppm in the diet of adult mongrel dogs and adult Sprague Dawley rats. In the dogs RBC cholinesterase activity was depressed 35% when coumaphos was administered in the diet at 50 ppm for 12 weeks. Serum cholinesterase activity was depressed 18% at 2 ppm, 42% at 5 ppm, 59% at 10 ppm, and 68% at 50 ppm over the same 12 week period. Activity returned to normal in 3 weeks. No clinical signs of toxicity were reported (Vaughn, et. al. 1958, MRID 00005384). The dog study does not satisfy the data requirements because the histopathology was inadequate. In the rats RBC cholinesterase activity was depressed at 40 ppm after 8 and 16 weeks. Serum cholinesterase activity was depressed in females at 2, 5, and 20 ppm at 8 and 16 weeks and in males at 10 ppm at 8 weeks. (Vaughn, et al. 1958, MRID 00005504). The rat study should have been performed on weanling rats to determine the toxicity of coumaphos during physical and sexual development and therefore does not meet data requirements.

Chronic Toxicity

An acceptable oncogenicity study reported no observed carcinogenic effect from coumaphos fed at 10 ppm and 20 ppm for two years in the diet of rats and mice (NCI 1979, MRID 05009938).

An inadequate chronic feeding study in rats (Doull, et al. 1960, MRID 00005473) reported a NOEL of 5 ppm in the diet. Depression of cholinesterase activity was reported at 10 ppm and higher dose levels in serum erythrocytes and submaxillary glands. At 25 and 100 ppm there was increased mortality and at 100 ppm fasciculations and infrequent convulsions were reported. The histopathology was inadequate because only 5 animals per dose were studied and no clinical studies were performed. The study therefore does not meet the data requirements.

An inadequate 3 generation mouse reproductive effects study reported a NOEL of 10 ppm. No effects on reproduction were observed which could not be attributed to maternal toxicity (Doull, et. al. 1962, MRID 0005148). Due to the inadequate histopathology the study does not meet the data requirements.

Data on the metabolism of coumaphos are incomplete. Four phosphorous-containing metabolities were identified (diethyl phosporothioic acid, phosphoric acid, diethyl phosphoric acid, and de-ethylated derivative of coumaphos) but their time and dose relationship was not quantified. The disposition of the complex leaving group was not followed (Krueger, et al. 1959, MRID 05004087, Vickery, MRID 0512220).

Toxicology Summary -- Coumaphos Formulations

One study is available on a 50% wettable powder (WP) formulation which reports an acute LD_{50} for male rats of 363 mg/kg (Lamb and Anderson, 1974, MRID 00005416). A second study using a 25% wettable powder formulation reported an acute LD_{50} of 22.5 mg/kg in male rats and 13.5 mg/kg in female rats (Hecht, 1958, GS0018003). Further testing is required to resolve the apparent contradication in the data, particularly because the 25% WP formulation is reported to be as toxic as some technical material.

An acceptable study shows that a 50% WP formulation has an acute dermal LD_{50} of greater than 2 mg/kg placing the formulation in Toxicity Category III (Lamb and Anderson 1974, MRID 00005416). An acceptable eye irritation study on a 50% WP formulation showed irritation and corneal damage to persist after 21 days placing the formulation in Toxicity Category I for eye irritation (Lamb and Matzkanin 1975, MRID 00005415).

Toxicity Hazard Assessment

Technical coumaphos has a very high acute oral toxicity. No carcinogenic effect has been reported. The 50% WP has been shown to have a very low acute dermal toxicity but to cause severe eye irritation.

Summary of Major Data Gaps

The major data gaps for this chemical are most of the acute studies on the technical chemical and end-use products, and, subchronic oral toxicity, subchronic 90 day dermal toxicity, chronic feeding, teratogenicity, reproductive effects, mutagencity, and metabolism on the technical chemical. No testing is required on the manufacturing-use products because the testing required on the technical will be used to support the registrability of the manufacturing-use product.

VII

Residue Chemistry

Residue Chemistry - Technical Coumaphos

Residue Chemistry Profile

Coumaphos is an organophosphorus insecticide applied to animals topically in the form of dusts, sprays, dips, and pour-ons. The dusts and liquid formulations act topically as well as systemically to control certain insects and parasites. The systemic products control internal parasites by the absorption of the active ingredient through the skin (ruminants, non-ruminants, and poultry).

The metabolism of coumaphos in animals is adequately defined by the available data. The primary residue of concern is coumaphos per se and its oxygen analog. (MRID 05004087, 00005454, 00005323, 05003806, 05012748, 05004483, 00005401, 05003806, 00005332, 00005392, 05100522, 05008968, 00005450).

The metabolism of coumaphos in plants is not of concern because coumaphos is not applied to crops.

Three different analytical procedures have been developed for the detection of coumaphos residues and all have been evaluated in EPA laboratories and found acceptable for the collection of residue data and enforcement of established tolerances. The procedures are 1) spectrofluorophotometry, 2) gas-liquid chromatography, and a modified photofluorometric method (MRID 05004066, 000005308, 00005328, 00005342, 00005289, 00005438, 00005080, 00005509, 05004211, 05017521, 05006630, 00005437).

The available residue data are adequate to support existing tolerances. They include data for coumaphos and its metabolite. These data are cited in Table A- 4 under "Residue Data; Milk, Meat and Eggs".

Studies conducted with both non-labeled and ^{32}p-labeled coumaphos show that when animals and poultry are treated with coumaphos according to label recommendations, there will be no residues in eggs, milk, meat, fat and meat by-products in excess of the established tolerances. (See Table A-4, "Residue Data; Milk, Meat and Eggs").

U.S. tolerances are adequately supported by residue data for coumaphos, 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl)phosphorothioate and its oxygen analog, 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphate, in or on raw agricultural products. These tolerances (40 CFR 180.189) are as follows:

1 ppm - in or on meat, fat and meat by-products of cattle, goats, hogs, horses, poultry, and sheep.

0.5 ppm - in milk fat (reflecting negligible residues in milk).

0.1 ppm - in eggs.

Based on the tolerances, the theoretical maximum residue contribution (TMRC) of total coumaphos is calculated to be 0.22 mg/day/1.5 kg (unverified printout of Acceptable Daily Intake, 40 CFR 180.189, coumaphos, February 9, 1981.) This figure is based on the average adult eating pattern and on the assumption that milk, meat, fat, meat by-products, and eggs contain residues which meet the respective tolerance levels.

Temporary Codex Maximum Residue Levels are 1 ppm in poultry and fat of cattle, 0.5 ppm in fat of sheep, pigs, goats, milk and milk products, and 0.05 ppm in eggs. The Agency is unable to assess the adequacy of the Codex tolerances due to a lack of supporting data.

Summary of Major Data Gaps

There are no data gaps in Residue Chemistry.

VIII.

Ecological Effects

Ecological Effects Summary

There is one acceptable study on the ecological effects of coumaphos. It shows the 96 hour LC_{50} for technical coumaphos administered to mature scuds (*Gammarus fasciatus*) to be .15 ug/l (Sanders 1972, MRID 05017538). This study does not meet the Agency's Guidelines for testing because immature animals were not used; however, the study is acceptable because it shows that coumaphos is very highly toxic to aquatic invertebrates. There are no acceptable studies on the effects of coumaphos on plants or non-target insects.

Summary of Major Data Gaps

The data gaps for this chemical are the avian single-dose LD_{50}, the avian dietary LC_{50}, the fish acute LC_{50}, and an acute toxicity to aquatic invertebrates.

IX

Efficacy

Efficacy Summary

The review of coumaphos data is limited to efficacy data only as they relate to public health applications. The Agency has provided for the waiver of efficacy data submission as part of the registration process in all other instances (44 FR 17932; May 11, 1979).

The public health applications of coumaphos are limited to the pesticide's use to control fleas, lice, and ticks on dogs and dog bedding.

Products registered for use on dogs and dog bedding and covered by this Standard are a 0.5% dust and a 1% pressurized liquid. The pressurized liquid product that is .25% coumaphos and 0.5% trichlorfon (0,0-Dimethyl 2,2,2-trichloro-1-hydroxyethyl phosphonate) is a double-active ingredient product and is therefore not registrable under this Standard.

Available data indicate that coumaphos in various formulations and at a concentration as low as 0.2% is effective in achieving some degree of control of fleas, lice, and ticks on dogs (MRID GS0018002, 00005087, 00005200, 00005326, 00005344, 00005088, 00005211).

Available data also indicate that a 0.5% coumaphos dust formulation controls fleas and ticks on dog bedding, (MRID GS0018001). An *in vitro* laboratory study showed that coumaphos ranging in concentration from .05% to 3.2% is effective against adult fleas (*Xenopsylla cheopis*), effectiveness reaching 100% at the 0.4% concentration. Coumaphos was somewhat less effective in controlling larvae of *X. cheopis*; 100% control was reached at the 3.2% concentration (MRID 05007632).

There appear to be several factors which may influence the efficacy of coumaphos. Some of these factors are: animal hair coat (length and type), method of application, species or type of pest, and amount of active material applied. Stuart (1959, GS0018001) noted problems in obtaining control of fleas when hair coat was thick and matted. Genung (GS0018002) presents data which seems to indicate more rapid control of ticks following application by washing as opposed to coumaphos applied as a dust. Stuart and Brewster (MRID 00005086) observed greater ease in controlling fleas as opposed to obtaining similar control of ticks. Stuart (GS0018001) observed "light dusting" of young pups did not result in as rapid or complete control as a heavier dusting applied to adult animals.

Summary of Major Data Gaps

The data deficiencies for coumaphos are related to the efficacy of the 0.5% dust in controlling lice on dogs and dog bedding. There are studies which indicate that the 0.5% dust and the 1% dust are effective against lice infesting several species of agricultural animals and their bedding. Some exemplary studies are Smith and Richards, 1955, (MRID 00005352), Knapp, 1962, (MRID 05011422), Bayvet, 1971, (MRID 00005028), Minter, 1970, (MRID 00005033), and Kohler, 1967, (MRID 00005200). By extrapolation from the large animal studies, the Agency assumes that the 0.5% dust is effective in controlling lice on dogs and dog bedding and thus the absence of data does not constitute a data gap.

Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this Standard. The bibliography is divided into 4 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard -- this section is cross-referenced by numerical identifiers, for easy access to studies cited in the Standard; (2) citations examined and judged to be inappropriate for use in developing the Standard; (3) standard reference material; and (4) potentially useful studies identified too late in the process of developing the standard to be considered. The fourth section cites the studies identified by the basic producer as being absent from the computerized search of the literature. The studies were identified too late to be given a formal review. This section also includes a single citation for a group of studies submitted in support of a flowable coumaphos product. Any of the studies in Section Four that, upon review, fill data gaps, will then be considered as amendments to the Guidance Package. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the agency, we have sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. We have attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation, an eight-digit numeric identifier. This number is unique to the citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever we could confidently identify one, we have chosen to show a personal author. When no individual was identified, we have shown an identifiable laboratory or testing facility as author. As a last resort, we have shown the first known submitter as author.

   b. Document Date. When the date appears as four digits with no question marks, we took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), we were unable to determine or estimate the date of the document.

   c. Title. This is the third element in the citation. In some cases it has been necessary for our bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

   d. Trailing Parentheses. For studies submitted to us in the past, the trailing parenthese include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

      (1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

      (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

      (3) Submitter. The third element is the submitter, following the phrase "submitted by". When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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Section One:
Citations Considered to be Part of the Data Base Supporting Registration Under the Standard
(References Listed by MRID Numbers)

MRID	Citation
00005028	Bayvet (1971)
00005033	Minter, R.W. (1970)
00005034	Huggins, K.G. (1970)
00005040	Olson, T.J. (1971)
00005042	Chemagro Corporation (1971)
00005047	Chemagro Corporation (1967)
00005048	Chemagro Corporation (1967)
00005051	Chemagro Corporation (1968)
00005056	Chemagro Corporation (1963)
00005074	Anderson, C.A. (1959)
00005080	Chemagro Corporation (1969)
00005081	Chemagro Corporation (1969)
00005082	Industrial Bio-Test Laboratories (1974)
00005087	Stuart, W.R. (1960)
00005088	Bayvet (1961)
00005148	Doull, J., Root, M., and Cowan, J. (1962)
00005161	Anderson, C.A. (1959)
00005186	Bayvet (19??)
00005187	Chemagro Corporation (1962)
00005188	Chemagro Corporation (1962)
00005189	Chemagro Corporation (1962)
00005190	Young, J.W. (1962)
00005192	Costello, J.R. (19??)
00005193	Chemagro Corporation (1957)
00005195	Anderson, C.A. (1958)
00005200	Kohler, P.H. (1967)
00005207	Bayvet (1967)
00005208	Bayvet (1965)
00005210	Bayvet (1964?)
00005211	Skaptason, J.S., MacDougall, D. (1960)
00005214	Chemagro Corporation (1964)
00005235	Chemagro Corporation (1964)
00005278	Waskeski, D.M. (1953?)
00005289	Adams, J. (1964)
00005293	Chemagro Corporation (1966)
00005295	Chemagro Corporation (1966)
00005307	Rose, W.B.; White, C.E. (1971)
00005308	Mobay Chemical Corporation (1964)
00005317	Chemagro Corporation (1964)
00005326	Williams, G.M. (1959)
00005328	Adams, J.M. (1961)
00005329	Chemagro Corporation (1963)
00005331	Chemagro Corporation (1961?)
00005332	Kruegar, H.R.; Casida, J.E.; Niedermeier, R.P. (1961)
00005333	Chemagro Corporation (1960)
00005336	Chemagro Corporation (1964?)

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MRID	Citation
00005338	Chemagro Corporation (1966)
00005339	Chemagro Corporation (1967)
00005342	Adams, J.M. (1963)
00005344	Skaptason, J.S. (1959)
00005345	Chemagro Corporation (1966)
00005352	Smith, C.L., Richards, R. (1955)
00005384	Vaoughn, G., Deininger, E., and Doull, J. (1958a)
00005392	Chemagro Corporation (1959)
00005395	Adelman, D. (1958)
00005396	Gronberg, R.R. (1958)
00005399	Gronberg, R.R. (1958)
00005400	Anderson, C.A. (1959)
00005401	Radeleff, R.D.; Claborn, H.V. (1957?)
00005402	Robbins, W.E.; Hopkins, T.L.; Darrow, D.I.; Eddy, G.W. (1959)
00005415	Lamb, D.W., and Matzkanin, C.S. (1975)
00005416	Lamb, D.W., and Matzkanin, C.S. (1975)
00005417	Bayvet (1974)
00005433	Caswell, R.L. (1962)
00005435	Chemagro Corporation (1966)
00005437	Chemagro Corporation (1968)
00005438	Thornton, J.S. (1968)
00005439	Chemagro Corporation (1968)
00005440	Chemagro Corporation (1960?)
00005441	Chemagro Corporation (1961)
00005448	Anderson, C.A. (1959)
00005450	Dourrough, H.W.; Brady, O.E., Jr.; Timmerman, J.A.; Arthur, B.W. (1959)
00005451	Anderson, C.A. (1959)
00005453	Anderson, C.A. (1959)
00005454	Dourrough, H.W.; Brady, U.E., Jr.; Timmerman, J.A.; Arthur, B.W (1959)
00005456	Chemagro Corporation (1960)
00005473	Doull, J., Vesselinovitch, D., Fitch, R., Root, M., and Meskauskas, J. (1960)
00005479	Gronberg, R.R. (1958)
00005480	Chemagro Corporation (1960)
00005483	Chemagro Corporation (1959?)
00005485	Chemagro Corporation (1962)
00005486	Chemagro Corporation (1962)
00005490	Ditman, L.P. (1963)
00005491	Chemagro Corporation (1963)
00005492	Chemagro Corporation (1961)
00005493	Chemagro Corporation (1961)
00005496	Narcisse, J.K. (1967)
00005504	Vaughn, G., Deininger, E. and Doull, J. (1958b)

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MRID	Citation
00005509	Bayvet (1968)
00005510	Chemagro Corporation (1968)
00005511	Chemagro Corporation (1969)
00005526	MacDougall, D. (19??)
00005528	Bloom, D. (1969)
00005822	Chemagro Corporation (1963)
00005830	Chemagro Corporation (1964)
00005831	Chemagro Corporation (1964)
00005832	Chemagro Corporation (1964)
00005833	Chemagro Corporation (1964)
00005834	Chemagro Corporation (1964)
00005837	Chemagro Corporation (1961)
00005838	Chemagro Corporation (1961)
00005840	Chemagro Corporation (1960)
00005842	Chemagro Corporation (1960)
00021981	Chemagro Corporation (1964)
00021997	Mobay Chemical Corporation (1966)
050?????	Knapp, F.W. (1962)
05002073	Barney, J.E. II (1965)
05002075	Braithwaite, D.P. (1963)
05002340	Damico, J.N. (1966)
05002359	Askew, J.; Ruzicka, J.H.; Wheals, B.B. (1969)
05002360	Keith, L.H.; Alford, A.L. (1969)
05003797	Volpe, Y.; Mallet, Y.N. (1976)
05003798	Waskeski, D.M. (1966)
05003799	Zakrevsky, J.G.: Mallet, V.N. (1975)
05003806	Radeleff, R.D.: Claborn, H.V. (1960)
05004066	Anderson, C.A.: Adams, J.M.: McDougall, D. (1959)
05004087	Krueger, H.R.; Casida, J.E.; Neidermeier, R.P. (1959)
05004089	El-Refai, A.; Hopkins, T.L. (1965)
05004211	Bowman, M.C.; Beroza, M. (1967)
05004290	Kane, P.F.; Cohen, C. J.; Betker, W.R.; MacDougall, D. (1960)
05004395	Keith, L.H.; Garrison, A.W., Alford, A.L. (1968)
05004690	Hurwood, I.S. (1966)
05004483	Kaplanis, J.N.; Hopkins, D.E.; Treiber, G.H. (1959)
05004866	McKinley, W.P.; Read, S.I. (1962)
05005125	Burnett, E.M. (1970)
05005130	Hartmen, C.H. (1966)
05005579	MacRae, I.C.; Celo, J.S. (1974)
05005830	Matthysse, J.G.; Lisk, D. (1968)
05006145	Ackermann, H. (1969)
05006630	Oehler, D.D.; Eschle, J.L.; Miller, J.A.; Claborn, H.V.; Ivey, M.C., (1969)
05006806	Zwieg, G., ed.; Sherma, J., ed. (1972)
05007632	Fox, I., et al. (1966)

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MRID	Citation
05008968	Dorough, H.W.; Brady, U.E., Jr.; Timmerman, L.A.; Arthur, B.W. (1961)
05009242	Sanders, H.O. (1969)
05009938	National Cancer Institute (NCI) (1979)
05010096	Bowman, M.C., et al (1968)
05010317	Babad, H,; Herbert, W.; Goldberg, M.C. (1968)
05010318	Ross, R.T.; Biros, F.J. (1970)
05100522	Dorough, H.W.; Brady, U.E., Jr. Timmerman, J.A.; Arthur, B.W. (1961)
05012220	Vickery, D.S., and Arthur, B.W. (1960)
05012747	Kasimov, D.D. (1969)
05012748	Kasimov, D.D. (1969)
05012915	FAO working Party of Experts on Pesticide Residues (1973)
05013242	Dorough, H.W.; Brady, U.E., Jr.; Timmerman, J.A.; Arthur, B.W. (1961)
05014477	Pflugmacher, J.; Ebing, W. (1978)
05016099	Beroza, M.; Bowman, M.C. (1971)
05017521	McLeod, H.A.; Butterfield, A.G.; Lewis, D.; Phillips, W.E.J.; Coffin, D.E. (1975)
05017538	Sanders, H.O. (1972)
05108561	Thornburg, W. (1971)
GS0018001	Stuart, W. (1959)
GS0018002	Genung, W. (1959)
GS0018003	Hecht, G. (1958)
GS0018004	Johnston, C.D., and Scott, W.J. (1965)

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Product Chemistry

MRID	Citation
05006145	Ackermann, H. (1969) Duennshichtchromatographisch-enzymatischer Nachweis phosphororganishcer Insektizige: zum duennschichtechromatgraphischen Verhalten einiger weiterer Insektizide- Thin-layer chromatographic-enzymatic determination of organophosphorus insecticides: thin-layer chromatographic behaviour of some further insecticides. Journal of Chromatgraphy 44(2):414-418.
05010317	Babad, H,; Herbert, W.; Goldberg, M.C. (1968) Nuclear magnetic resonance studies of phosphorus (V) pesticides: Part I - Chemical Shifts of protons as a means of identification of pesticides. Analytica Chimica Acta 41(2):259-268.
05002073	Barney, J.E. II (1965) New spray tests for detecting organophosphorus compounds on thin-layer chromatograms. Journal of Chromatography 20(2):334-341.
00005208	Bayvet (1965) Confidential Ingredient Statement: Co-Ral 1% Ready-To-Use Spray. (Unpublished Study received June 4, 1965 under 11556-16; CDL:126968-D).
00005207	Bayvet (1967) Confidential Ingredient Statement: Co-Ral 1% Ready-To-Use Spray. (Unpublished study received May 1, 1967 under 11556-16; CDL:126968-C).
00005417	Bayvet (1974) Co-Ral Formulator's Manual for Dust Formulations. Unpublished study received Jan. 8, 1975 under 11556-49; CDL;140110-B).
00005528	Bloom, D. (1969) Stability Study: Moorman's Insecticide Dust with (R) Co-Ral. (Unpublished study received Aug. 22, 1969 under 1157-31; submitted by Moorman Manufacturing Co., Quincy, Ill.; CDL:005687-A).
05002075	Braithwaite, D.P. (1963) Detection of phosphorothioate pesticides, Nature (London) 200(4910):101.
00005433	Caswell, R.L. (1962) Report on Co-Ral: Determination of Sulfotepp. Method dated Nov. 15, 1962. Unpublished study received Nov. 15, 1962 under unknown admin. no.; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:124758-A).

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Product Chemistry

MRID	Citation
00005193	Chemagro Corporation (1957) Co-Ral (Formerly Bayer 21/199) for Experimental Use Only. Unpublished study received July. 1, 1957 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124847-A).
00005838	Chemagro Corporation (1961) Confidential Ingredient Statement: Co-Ral Livestock Duster (5% Dust). (Unpublished study received Mar.29, 1961 under 1F0306; CDL:092586-M).
00005188	Chemagro Corporation (1962) Chemagro Corporation Analytical Method: Assay of Technical Co-Ral by Ultraviolet Spectrophotometry. Method TMC-2.8 dated July 17, 1962. (Unpublished study received Oct. 24, 1962 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124761-B).
00005187	Chemagro Corporation (1962) Chemagro Corporation Analytical Method: Estimation of Active Ingredient in Co-Ral 25% Wettable Powders by Ultraviolet Spectrophotometry. Method TMC-2.6 dated July 25, 1962. Unpublished study received Oct. 24, 1962 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124761-A).
00005189	Chemagro Corporation (1962) Chemagro Corporation Analytical Method: Estimation of Chlorferron in Technical Co-Ral by Ultraviolet Spectrophotometry. Method TMC-2.10, dated June 7, 1962. (Unpublished study received Oct. 24, 1962 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124761-C).
00021981	Chemagro Corporation (1964) Co-Ral Parasiticide. (Unpublished study received Oct. 8, 1968 under unknown admin. no.; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:006897-A).
00005435	Chemagro Corporation (1966) Confidential Ingredient Statement: Co-Ral 25% Wettable Powder. (Unpublished study received Dec. 21, 1967 under 8F0678; CDL:092983-B).
00005345	Chemagro Corporation (1966) Confidential Ingredient Statement: Co-Ral Emulsifiable Concentrate: (1lb./gal.). (Unpublished study received on unknown date under 1F0306; CDL:092586-L).

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Section One:
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Product Chemistry

MRID	Citation
00005192	Costello, J.R. (19??) Co-Ral: Operating Procedure. (Unpublished study received Oct. 24, 1962 under unknown admin. no.; submitted by Bayvet, Shawnee Mission, Kans.; CDL:124761-O).
05002340	Damico, J.N. (1966) The mass spectra of some organophosphorus pesticide compounds. Journal of the Association of Official Analytical Chemists 49(5):1027-1045.
05013242	Dorough, H.W.; Brady, U.E., Jr.; Timmerman, J.A.; Arthur, B.W. (1961) Residues in tissues and eggs of poultry receiving Co-Ral (Bayer 21/199) in the feed. Journal of Economic Entomology 54(1):97-100.
05004089	El-Refai, A.; Hopkins, T.L. (1965) Thin-layer chromatography and cholinesterase detection of several phosphorothiono insecticides and their oxygen analogs. Journal of Agricultural and Food Chemistry 13(5):477-481.
05005130	Hartman, C.H. (1966) Phosphorus detector for pesticide analysis, Bulletin of Environmental Contamination and Toxicology 1(4):159-168.
05004290	Kane, P.F., et al. (1960) Assay of Co-Ral in Technical Material and Formulated Products. Journal of Agricultural and Food Chemistry 8(1):26-29.
05012747	Kasimov, D.C. (1969) Laboratornvi sintez ko-rala, mechenogo po P32 Laboratory synthesis of phosphorus-32 labeled Co-Ral. Trudy, Vsesoyuznyi Nauchno Issledovatel'skii Institut Veterinarnoi Sanitarii. Transactions, All-Union Scientific Research Institute of Veterinary Sanitation. 32:375-378.
05002360	Keith, L.H.; Alford, A.L. (1969) Supplementary interpretations of the NMR spectra of phosphorus pesticides. Analytica Chimica Acta 44(2):447-448.
05004395	Keith, L.H.; Garrison, A.W., Alford, A.L. (1968) The high resolution NMR spectra of pesticides. Organophosphorus pesticides. Journal of the Association of Official Analytical Chemists 51(5):1063-1094.

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Section One:
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Product Chemistry

MRID	Citation
00005526	MacDougall, D. (19??) Co-Ral. Pages 83-95, "In"? By ? N.P. (Also "In" unpublished submission received May 1, 1972 under 2749-135; submitted by Aceto Chemical Co., Inc., Flushing, N.Y. CDL:025450-A).
05004866	McKinley, W.P.; Read, S.I. (1962) Esterase inhibition technique for the detection of organophosphorus pesticides. Journal of the Assocation of Official Agricultural Chemists 45(2):467-473.
00021997	Mobay Chemical Corporation (1966) Confidential Ingredient Statement: Co-Ral 5.0% Dust (Livestock Duster). (Unpublished study received Oct. 8, 1968 under unknown admin. no.; CDL:006897-AG).
05014477	Pflugmacher, J.; Ebing, W. (1978) Zur Kenntnis des Elutionsverhaltens einiger pflanzenschutzmittelwirkstoffklassen bei der Galchromatographie. Evaluation of the elution behaviour of some classes of pesticides in gel chromatography. Journal of Chromatography 151(2):171-197.
00005307	Rose, W.B., White, C.E. (1971) Co-Ral: Formulator's Manual for Dust Formulations: Report No. 16425. Includes undated method. (Unpublished study receved June 4, 1971 under 3125-101; submitted by Mobay Chemical Corp., Agricultural Div., Kansas City, MO.; CDL:025735-A).
05010318	Ross, R.T.; Biros, F.J. (1970) Correlations between 31 chemical shifts and structures of some organophosphorus pesticides. Analytica Chimica Acta 52(1):139-141.
05003797	Volpe, Y.; Mallet, Y.N. (1976) A mechanism for the neat-induced fluorescence of coumaphos and related compounds and the identification of their metabolities in water. Analytica Chimica Acta 81(1):111-116.
00005278	Wasleski, D.M. (1953?) Colorimetric determination of Potasan in Coumaphos. Undated method. (Unpublished study received Sep. 20, 1965 under 11556-21; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans,; CDL:124734-A).
05003798	Wasleski, D.M. (1966) Colormetric determination of Potasan in Coumaphos. Journal of Agricultural and Food Chemistry 14(2):156-158.

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MRID	Citation
00005278	Waleski, D.M. (1953?) Colorimetric Determination of Potasan in Coumaphos. Undated Method. (Unpublished study received Sept. 20, 1965 under 11556-21; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:124734-A).
05003798	Wasleski, D.M. (1966) Colorimetric Determination of Potasan in Coumaphos. *Journal of Agricultural and Food Chemistry* 14(2):156-158.
00005190	Young, J.W. (1962) Co-Ral 25% Wettable Powder Field Storage Tests: Report No. 10002. (Unpublished study received Oct. 24, 1962 under unknown admin. no.; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:124761-E).

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Environmental Fate

MRID	Citation
05005579	MacRae, I.C.; Celo, J.S. (1974) The Effects of Organophosphorus Pesticides on the Respiration of Arotobacter vinelandii. Soil Biology and Biochemistry 6(2):109-111.

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Toxicology

MRID	Citation
00005148	Doull, J., Root, M., and Cowan, J. 1962. The Effect of Co-Ral in the Diet on the Reproduction of Mice: Report No. 10203. (Unpublished study received March 11, 1963, under unknown administration number; prepared by University of Chicago, Department of Pharmacology, submitted by Bayvet, Shawnee Mission, Kans.; CDL:109146-D).
00005473	Doull, J., Vesselinovitch, D., Fitch, R., Root, M., and Meskauskas, J. 1960. Chronic Toxicity of Co-Ral Fed to Rats for a Period of Two Years: Report No. 6089. (Unpublished study received December 14, 1961, under PP0299; prepared by University of Chicago, Departments of Pharmacology and Pathology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:09320-Y).
GS0018003	Hecht, G. (1958) The Acute Toxicity of Various Co-Ral Preparations to Rats, Report No 3405a, Farbenfabriken Bayer, West Germany, January 28, 1958 (Unpublished study; CDL:090319 and 090320).
GS0018004	Johnston, C.D., and Scott, W.J. (1965). GS13005 25W Potentiation Studies with Other Organophosphate Insecticides in the Rat. (Unpublished study received August 5, 1967, under 8F06481; prepared by Woodard Research Corp., submitted by Geigy Chemical Corp., Ardsley, N.Y.: CDL:091128-U).
05004087	Krueger, H.R.; Casida, J.E.; Niedermeier, R.P. (1959) Bovine metabolism of organophosphorus insecticides--Metabolism and residues associated with dermal application of Co-Ral to rats, a goat, and a cow. J. Agric. Food Chem. 7:182-188 (26A-0022).
00005416	Lamb, D.W., and Anderson, R.G. 1974. Acute Toxicity of Co-Ral 50% Wettable Powder to Rats and Rabbits: Report No. 41817. (Unpublished study received January 8, 1975, under 11556-49; prepared by Mobay Chemical Corp., submitted by Bayvet, Shawnee Mission, Kans,; CDL:140110-A).
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05003799	Zakrevsky, J.G.; Mallet, V.N. (1975) Determination of coumaphos and its oxygen analog in eggs by in situ fluorometry. Journal of the Association of Official Analytical Chemists 58(3):554-556.
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MRID	Citation
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MRID	Citation
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00005028	Bayvet. (1971) Synopsis of Biological Performance of Co-Ral 1% Dust Administered to Cattle with Shaker Cans for the Control of Cattle Lice and Horn Flies. Summary of studies 004549-B through 004549-M. (Unpublished study received Oct. 29, 1971 under 11556-4; CDL:004549-A).
05007632	Fox, I. et al. (1966) Toxicity of Various Insecticides to _Xenopsylla cheopis_. _American Journal of Tropical Medicine and Hygiene_. 15(4):611-613.
GS0018002	Genung, W. (1959) Letter and Table Describing Control of Brown Dog Tick. Bayvet Division, Cutter Laboratories, Inc.; Report No. 3948. (Unpublished study).
05011422	Knapp, F.W. (1962) Co-Ral as a Litter and Nest Dust to Control the Chicken Body Louse. _Journal of Economic Entomology_. 55(4):571-572.
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00005344	Shaptason, J.S. (1959) Co-Ral Treatment of Dogs. Report No. 4474. (Unpublished study received Dec. 16, 1959 under 1F0306; submitted by Chemagro Corp., Kansas City, Mo.; CDL:092080-Q).

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MRID	Citation
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00005352	Smith, C.L.; Richards, R. (1955) Evaluations of Some New Insecticides on Livestock and Poultry. Journal of Economic Entomology. 48(5):566-568. (Report no. 1190; also "In" unpublished submission received Apr. 4, 1958 under 1F0306; submitted by Chemagro Corp., Kansas City, Mo.; CDL:092081-F).
GS0018001	Stuart, W. (1959) Control of Pests on Dogs. Bayvet Division, Cutter Laboratories, Inc., Report No. 4467. (Unpublished study).
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MRID	Citation
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00005484	Anderson, C.A. (1959) Co-Ral residues in chicken tissues: Report No. 3765. (Unpublished study received Feb. 11, 1964 under PP0299; prepared in cooperation with Univ. of Hawaii, Dept. of Entomology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:090319-V).
00005447	Anderson, C.A. (1959) Co-Ral residues in chicken tissues: Report No. 3869(b). (Unpublished study received Mar. 10, 1961 under PP0299; prepared in cooperation with Univ. of California--Riverside, Dept. of Entomology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:090317-R).
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MRID	Citation
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00005170	Bayvet (1965) Supplement to Synopsis of Biological Performance of Co-Ral 0.25% Neguvon 0.5% Pressurized Spray for Ectoparasite Control on Dogs.
00005045	Bayvet (1967) Synopsis of analytical and residue information for dust application to cattle. Summary of studies 014008-B through 014008-G. (Unpublished study received Dec. 15, 1967 under 11556-19; CDL:014008-A).
05004061	Bellows, R.A., Rumsey, T.S., Kasson, C.W., Bond, J., Warnick, E.J., and Pahnish, O.F. (1975). Effects of organic phosphate systemic insecticides on bovine embryonic survival and development. Am. J. Vet. Res. 36:1133-1140.
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05004554	Bourne, S. (1978) Preservation of organophosphorus pesticides in water samples. Journal of Environmental Science and Health, Part B 13(2):75-86.
05004291	Brodeur, J., and DuBois, K.P. (1963) Comparison of acute toxicity of antichloinesterase insecticides to weanling and adult male rats. Proc. Soc. Exp. Biol. Med. 114:509-511.
05004213	Brun, G.L.; Mallet, V. (1973) Detection of organophosphorus pesticides by in situ fluorometry on thin-layer chromatograms. Journal of Chromatography 80(1):117-123.

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05009310	Burchfield, H.P.; Storrs, E.E. (1975) Analysis for organophosphorus insecticides and metabolities. Journal of Chromatographic Science 13(5):202-211.
05003134	Burke, J.A.; Holswade, W. (1966) A gas chromatographic column for pesticide residue analysis: retention times and response data. Journal of the Association of Official Analytical Chemists 49(2):374-385.
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00005489	Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. EC-212-62D: Report No. 11358. (Unpublished study received Feb. 11, 1964 under PP0299; CDL:090319-AA).
00005330	Chemagro Corporation (1963) Chemagro Corporation Residue Experiment No. KC-201-63D: Report No. 10923. (Unpublished study received on unknown date under PP0306; CDL:090321-D).

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00005341	Chemagro Corporation (1963) The Effect of Storage at 40°F on Co-Ral Residues in Milk: Report No. 11212. (Unpublished study received on unknown date under 1F0306; CDL:092586-F).
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00005836	Chemagro Corporation (1965) Recovery of Co-Ral from milk: Report No. 16197. (Unpublished study received Aug. 18, 1966 under 7F0612; CDL:090796-M).
00005337	Chemagro Corporation (1966) Chemagro Corporation Residue Experiment No. KC-200-67D: Report No. 19234. (Unpublished study including report nos. 19235 and 19351, received on unknown date under PP0306; CDL:090321-V).
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00005436	Chemagro Corporation (1967?) Reasonable grounds in support of the petition: Coumaphos. (Unpublished study received Dec. 21, 1967 under 8F0678; CDL:092983-C).
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05004292	Clear, M.H.; Fowler, F.R.; Solly, S.R.B.; Ritchie, A.R. (1977) Detection of organorphosphorus and carbamate pesticides in adipose tissue by thin-layer and gas-liquid chromatgraphy. New Zealand Journal of Science 20(2):221-224.

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00021983	Dale, L.B. (1968). Co-Ral. (Unpublished study received October 8, 1968, under unknown administrative number; submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:006897-E).
00005487	Ditman, L. P. (1962) Chemagro Corporation Residue Experiment No. EC-212-62H: Report No. 9912a. (Unpublished study received Feb. 11, 1964 under PP0299; prepared by Univ. of Maryland, Dept. of Entomology, Insecticide Laboratory, submitted by Chemagro Corp., Kansas City, Mo.; CDL:090319-Y).
00005107	Dorko, N.M. (1964). Co-Ral E.C. 1 lb/gal Cattle Toxicity Trial: Report No. 13684. (Unpublished study received August 24, 1964, under 11556-23; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:007104-S).
00005335	Doull, J. and Root, M. (1966). Effect of Co-Ral in the Diet on the Blood Cholinesterase Activity of Male and Female Dogs: Report No. 18726. (Unpublished study received on unknown date under PP0306; prepared by University of Chicago, Toxicity Laboratory, submitted by Chemagro Corp., Kansas City, Mo.; CDL:090321-Q).
00005147	Doull, J., Root, M., and Cowan, J. (1962). Ninety-Day Feeding Studies with Co-Ral in Male and Female Rats and Dogs Fed a Milk Diet: Report No. 10200. (Unpublished study received March 11, 1963, under unknown administration number; prepared by University of Chicago, Department of Pharmacology; submitted by Bayvet, Shawnee Mission, Kans.; CDL:109146-C).

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00005382	DuBois, K.P. (1958). The Dermal Toxicity of Co-Ral (Bayer 21/199) to Rats: Report No. 2452. (Unpublished study received October 8, 1959, under 1F0306, prepared by University of Chicago, Department of Pharmacology, submitted by Chemagro Corp., Kansas City, Mo.; CDL:090325-M).
00005146	DuBois, K.P. (1962). Comparison of the Toxicity of Co-Ral to Normal and Partially Hepatectomized Female Rats: Report No. 10116. (Unpublished study received March 11, 1963, under unknown administration number; prepared by University of Chicago, Department of Pharmacology, submitted by Bayvet, Shawnee Mission, Kans.; CDL:109146-B).
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05006314	Eschle, James L., Oehlem, D.D., Hogan, B.F., and Ivey, M.C. Coumaphos on cable type backrubbers: control of horn flies and determination of residues in milk of dairy cattle. Jour. Economic Entomology, Vol. 66, No. 1, 290-291.
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05004478	Galley, D.J. (1972) Persistence of Some Organophosphorus Insecticides in Henhouse Litter. Pesticide Science 3(1):119-123.
05002142	Getz, M.E. (1963) The determination of organophosphate pesticides and their residue by paper chromatography. Pages 9-25, "In" Residue Reviews: Residues of Pesticides and Other Foreign Chemicals in Foods and Feeds. Vol. 2. Edited by F.A. Gunther. New York: Springer.
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05006440	Gulbransen, B., Laws, L., and Connell, J.A. (1977). Effect of dipping on the growth rate of grazing cattle. Queensland J. Agric. Anim. Sci. 34(1):99-101.
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05006182	Hunt, L.M., and McCarty, R.T. (1972). Effects of some organophorphorus insecticides on vitamin E and other blood constituents and on the apparent inducement of diarrhea in neonatal calves. Bull. Environ. Contam. Toxicol. 8(5):297-305.
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05005516	Katz, M. (1961) Acute Toxicity of Some Organic Insecticides to Three Species of Salmonids and the Threespine Stickleback. *Transaction of the American Fisheries Society* 90:264-268.
05011426	Khan, M.A., Kramer, T., and Avery, R.J. (1961). Organophosphate poisoning in cattle with particular reference to Co-Ral. Can. Vet. J. 2(6):207-211.
05005518	Khan, M.A., and Lawson, J.E. (1965). Summer treatments for cattle grub control and their effects on horn flies and cattle weight gains. Can. J. Anim. Sci. 45(1):43-50.
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05004555	Kreitzer, J.F.; Spann, J.W. (1963) Tests of Pesticidal Synergism with Young Pheasants and Japanese Quail. Bulletin of Environmental Contamination and Toxicology 9(4):250-256.
05004077	Lin, T., and Dorough, H.W. (1974). Influence of insecticide exposure on the in vivo and in vitro metabolic activity of rats. Arch. Environ. Contam. Toxicol. 2(4):364-377.
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05004309	Mallet, V. N.; Volpe, Y. (1978) Degradation of coumaphos in distilled water as a function of pH. Analytica Chimica Acta 97(2):415-418.
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05012621	Malone, J.C. (1962). The toxicity of Coroxon/pheno-thiazine
05004314	Moscioni, A.D., Engel, J.L., and Casida, J.E. (1977). Kynurenine formamidase inhibition as a possible mechanism for certain teratogenic effects of organophosphorus and methylcarbamate insecticides in chicken embryos. Biochem. Pharmacol. 26:2251-2258.
05002567	Mozier, J.O. (1969). Advances in cattle ectoparasite control with a discussion of some problems related to treatment with systemic insecticides. J. Am. Vet. Med. Assoc. 154(10):1206-1213.
05011425/ 00005167	Mozier, J.O., and Allen, A.D. (1969). Toxicity Evaluation of Co-Ral 0.5 lb/gal Emulsifiable Concentrate: Report No. 25343. (Unpublished study received January 23, 1970, under 11556-26; prepared by Chemagro Corp., submitted by Bayvet, Shawnee Mission, Kans.; CDL:014012-B).
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